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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,431	08/05/2003	Wolfgang Guba	21152	8300

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HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
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EXAMINER
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STOCKTON, LAURA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 08/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/634,431

**Applicant(s)**

GUBA ET AL.

**Examiner**

Laura L. Stockton, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-16 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

**Claims 1-16 are pending in the application.**

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

In claim 4, under the definition of R<sup>3</sup>, "cyclohexyl" is misspelled.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

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matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support in the specification or the originally filed claims can be found for the list of compounds under the proviso in instant claim 1. Applicants did not state where {page number(s) and line number(s)} support could be found in the specification or the originally filed claims for the list of compounds in the proviso. Applicants should specifically point out the support for any amendments. See M.P.E.P. §§ 714.02 and 2163.06. Therefore, claim 1 lacks written description as such.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 10, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaya et al. {U.S. Pat. 4,649,146}.

***Determination of the scope and content of the prior art (MPEP §2141.01)***

Applicants claim thiazole compounds. Takaya et al. teach thiazole compounds that are structurally similar to the instant claimed compounds. See formula (I) in Takaya et al., for example, wherein R<sup>1</sup> is lower alkyl; R<sup>2</sup> is arylamino; R<sup>3</sup> is N-containing unsaturated heterocyclic group which may be substituted; Q is -CO-, n is 1 {column 1, lines 34-65; column 10, lines 15-20; column 11; columns 21-25; and especially Example 1

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(column 25); Example 4 in column 26; and Example 27 (column 31)}.

***Ascertainment of the difference between the prior art and the claims***

***(MPEP §2141.02)***

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

***Finding of prima facie obviousness--rational and motivation (MPEP***

***§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., cardiotonic activity).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at

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the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating heart disease. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

### ***Response to Arguments***

Applicants' arguments filed June 9, 2005 have been fully considered. Applicants argue that: (1) there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the teachings in Takaya et al. and expectation of success; (2) Takaya et al. fail to teach, suggest or motivate a skilled artisan to practice the instantly claimed compounds; (3) the instant claims are species of the general formula recited in Takaya et al. and therefore, alleges patentability; (4) there is no suggestion or motivation

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in Takaya et al. to select a sub-genus with the expectation that it would successfully act as a neuropeptide Y antagonist; and (5) an "obvious to try" scenario has been applied.

All of Applicants' arguments have been considered but have not been found persuasive. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Applicants claim thiazole compounds. Takaya et al. teach thiazole compounds that are structurally similar to the instant claimed compounds. See formula (I) in Takaya et al., for example, wherein R<sup>1</sup> is lower alkyl;



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R<sup>2</sup> is arylamino; R<sup>3</sup> is N-containing unsaturated heterocyclic group which may be substituted; Q is -CO-, n is 1 {column 1, lines 34-65; column 10, lines 15-20; column 11; columns 21-25; and especially Example 1 (column 25); Example 4 in column 26; and Example 27 (column 31)}. Takaya et al. generically teach Applicants' claimed compounds. The examples in Takaya et al. further direct one skilled in the art to the instant claimed compounds. Note especially Example 4 (column 26) and Example 27 (column 31). It is disagreed that instant claim 1 is directed to specie. Instant claim 1 cover a genus of compounds and said genus overlaps with the teachings in Takaya et al.

There is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by Applicants in order to support a legal conclusion of obviousness. In re Dillon, 16 U.S.P.Q. 2d 1897 (Fed. Cir. 1990). The

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only requirement is that the prior art reference provide motivation to prepare the claimed compounds.

In response to Applicants' argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). For all the reasons given above, the instant claimed invention would have been obvious to one skilled in the art.

### **Conclusion**

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action.

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Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

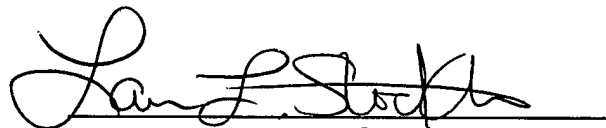
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is

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(571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

August 11, 2005